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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,122	03/20/2004	Andreas M. Papas	YH-AquaE	8910
41546	7590	10/12/2007	EXAMINER	
DONNA J. RUSSELL 1492 ANTHONY WAY MT. JULIET, TN 37122			SILVERMAN, ERIC E	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			10/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/805,122

Applicant(s)

PAPAS ET AL.

Examiner

Eric E. Silverman, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-23 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-15, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response, filed 9/7/2007, has been received. Applicant elected Group I, claims 1 – 15, 22, and 23 without traverse. Applicants further elected a species of tocopherols and tocotrienols as the species of lipophile. The election of species is with traverse. The traverse is on the basis that the composition of Group I may be used to solubilize a variety of lipophiles, and thus, according to Applicant, the different lipophiles need not be examined separately. Absent an explicit admission that the various species are obvious over one another, this argument falls short. Rejoinder of the non-elected species will be considered if a generic claim becomes allowable. Applicants submitted that claims 6 – 15, 22 and 23 read on the elected species, and it is given that claims 1 – 5 are generic to the elected species.

Pursuant to the election and amendment, claims 1 –11, 13 – 15, 22 and 23 are considered on the merits in this action.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 8, 10, 11, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,824,638 to Burnsides et al.

Burnsides discloses water-in-oil emulsions for delivery of insulin (claim 1). In one embodiment (table 13, item 19I), the emulsions contain vitamin E TPGS and linoleic acid in a ratio of 1:5.6 (8.6:48.6), which is within the ratio explicit limits of instant claims 5, 8, and 10 and close enough to a 1:4 ratio to read on "about 1:4" as recited in claim

11. A w/o emulsion is potentially useful for either topical or oral delivery, satisfying the limitations of instant claims 22 and 23.

Claims 1, 2, 5, 6, 8, 10, 11, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,883,103 to Burnsides et al.

Burnsides discloses water-in-oil emulsions for delivery of acyclovir (abstract, claim 1). In one embodiment (table 16, item 16C), the emulsions contain vitamin E TPGS and linoleic acid in a ratio of 1:5.6 (8.6:48.6), which is within the ratio explicit limits of instant claims 5, 8, and 10 and close enough to a 1:4 ratio to read on “about 1:4” as recited in claim 11. A w/o emulsion is potentially useful for either topical or oral delivery, satisfying the limitations of instant claims 22 and 23.

Claims 1, 2, 5, 6, 7, 8, 10, 11, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/29300 (the ‘300 reference).

The ‘300 reference discloses preconcentrates of fenofibrate which form emulsions upon addition of water (abstract, examples). The composition in Examples 1 and 2 contain Vitamin E TPGS and linoleic acid in ratios of 1:1.2 and 1:1.7, respectively. Water is added in an amount of 50 – 100 times the amount of the preconcentrate to form the emulsions (page 11). W/o emulsions are potentially useful as either topical or oral formulations, meeting the limitations of claims 22 and 23.

Claim Rejections - 35 USC § 103

Claims 3, 4, 9, and 13 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,824,638 to Burnsides et al. in view of US 5,883,103 to

Burnsides et al., WO 99/29300 and Roy et al., in FEBS Lett. 2002 October 23; 530(1-3):17-23.

The teachings of the Burnsides references and the '300 reference were discussed individually above. Each of the references teach the combination of linoleic acid and vitamin E TPGS for making emulsions of a different active agent. The ratio of the linoleic acid and vitamin E TPGS varies from example to example. Taken in combination, these references suggest to the artisan that the combination of linoleic acid and vitamin E TPGS is useful in making pharmaceutically acceptable emulsions of a variety of active agents. The references further suggest that the ratio of linoleic acid to vitamin E TPGS is varied depending on the specific formulation.

What is lacking is a teaching of the tocopherols and tocotrienols of the instant claims.

Roy teaches that vitamin E is essential for neurological function, and that a deficiency of same causes adverse symptoms. Further, vitamin E activity is found in eight natural substances: alpha-, beta, gamma- and delta tocopherol, and alpha-, beta-, gamma-, and delta- tocotrienol (introduction).

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the various known tocopherols and tocotrienols as the active agent in an emulsion composition having linoleic acid and vitamin E TPGS. Such compositions are known to be useful for formulating a variety of active agents, and thus the artisan would believe that vitamin E substances could also be formulated successfully in a similar manner. With regard to the ratio of linoleic acid and vitamin E

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TPGS, the art suggests that this parameter is optimizable, and that it will vary depending on the specifics of the formulation (including the nature of the active agent and other excipients). The eight vitamin E compounds are used for their known physiological benefits. The ratio or amounts of the various tocopherols and tocotrienols is a matter of dosing, which is routine in the art. The artisan selects the proper dose depending on the condition of interest, the patient's species, gender, and medical condition, and so forth, with the object of treating the condition of interest.

Since the combination of linoleic acid and vitamin E TPGS appears to be well recognized for use in formulating useful emulsion of pharmaceuticals, the artisan would expect to succeed in formulating the vitamin E substances in a linoleic acid and vitamin E TPGS containing emulsion. The artisan would further enjoy a reasonable expectation of success in optimizing the ratio of the linoleic acid and vitamin E TPGS, and optimizing the dosage of the various tocopherols and tocotrienols.

Conclusion

No claims are allowed. No claims are free of the prior art.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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